K120648

JUN 1 4 2012

5. 510(k) Summary

Date Prepared:

February 28, 2012

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902

Telephone: (301) 251-1092
Fax: (203) 602-3785
Contact: Jyh-Shyan Lin

Device Trade Name:

Synapse 3D Lung and Abdomen Analysis

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name:

Picture Archiving and Communications System (PACS)

Panel:

Radiology

Product Code:

LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

FUJIFILM Medical Systems U.S.A., Inc.
Synapse 3D Lung and Abdomen Analysis (V3.0) 510(k)

Predicate Device:

- Synapse 3D Lung and Abdomen Analysis (K103720), FUJIFILM Medical Systems U.S.A., Inc.
- Pulmonary Workstation 2 (K083227), VIDA Diagnostics, Inc.

Description of the Device

Synapse 3D Lung and Abdomen Analysis (V3.0) is the updated version of previously-cleared Synapse 3D Lung and Abdomen Analysis software (cleared by CDRH via K103720 on 03/16/2011).

Synapse 3D Lung and Abdomen Analysis is used in addition to Synapse 3D Base Tools (K120361, cleared on April 6, 2012) to analyze the images acquired from CT. Synapse 3D Lung and Abdomen Analysis is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning of DICOM compliant medical images. This product is not intended for use with or for the primary diagnostic interpretation of mammography images.

Synapse 3D Lung and Abdomen Analysis (V3.0) is an application that performs the CT lung analysis/airway and abdomen 2D and 3D fat analysis.

- Lung analysis/Airway
  Lung analysis/Airway is an application using non-contrast and contrast enhanced computed tomographic images of the lung which provides custom workflows and UI, and reporting functions including boundary detection and volume calculation for pulmonary nodules in the lung based on the location specified by the user, segmentation of bronchial tubes in the lung, approximation of air supply region by the user specified bronchial tube, identifying, displaying and processing low absorption regions in the lung.
- 2D Fat Analysis (Unchanged from the cleared version K103720)
  2D Fat Analysis is an application which can use single slice (2-dimensional) non-contrasted CT images to calculate subcutaneous fat and visceral fat areas.
- 3D Fat Analysis (Unchanged from the cleared version K103720)
  3D Fat Analysis is an application which can use volume (3-dimensional) non-contrasted CT images to calculate subcutaneous fat and visceral fat areas and volumes.

The following common image processing functions are available to support the analysis of the lung and abdomen CT images. These functions belong to and are provided by Synapse 3D Base Tools (K120361) that is used with Synapse 3D Lung and Abdomen Analysis (V3.0).

- Window width and window level.
- Zooming, panning, flip, rotate.
- Measurement of lengths, areas, etc.
- Adding annotations on an image.
- Extraction and Deletion of 3D objects: Editing of mask areas using the smart cut feature.
- 3D clipping: The display area can be specified for 3D display.
- Creation of video files: Video files with 2D or 3D display can be created.

FUJIFILM Medical Systems U.S.A., Inc.
Synapse 3D Lung and Abdomen Analysis (V3.0) 510(k)

Indication for Use

Synapse 3D Lung and Abdomen Analysis is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Lung and Abdomen Analysis accepts DICOM compliant medical images acquired from CT.
This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to Synapse 3D Base Tools, Synapse 3D Lung and Abdomen Analysis is intended to;

> use non-contrast and contrast enhanced computed tomographic images of the lung, provide custom workflows and UI, and reporting functions for lung analysis including boundary detection and volume calculation for pulmonary nodules in the lung based on the location specified by the user, segmentation of bronchial tubes in the lung, approximation of air supply region by the user specified bronchial tube, identifying, displaying and processing low absorption regions in the lung.

> use non-contrasted CT images and calculate subcutaneous fat and visceral fat areas in 2D and both volumes in 3D.

Technological Characteristics

Synapse 3D Lung and Abdomen Analysis introduces no new safety or efficacy issues other than those already indentified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Testing

Synapse 3D Lung and Abdomen Analysis is tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Synapse 3D Lung and Abdomen Analysis software, which is found to be safe and effective and substantially equivalent to the currently-cleared predicate device. Testing involved system level functionality test, segmentation accuracy test, measurement accuracy test, interfacing test, usability test, serviceability test, labeling test, as well as the test for risk mitigation method analyzed and implemented in the risk management process, in the same manner as our previously-cleared predicate device.

New to this submission is lung volume analysis (approximation of air supply region). To establish that our device is as safe and effective as the predicate device, Fujifilm performed the following two nonclinical tests for the proposed device:

(a) Simulated test

Test protocol summary

Prepared a simulated image data set for air supply region approximation with known air supply volume for each bronchus. Then performed air supply region approximation and compared the measured results with known volumes.

Acceptance criteria

Pass if the measured results are within ±5% of known values.

(b) Test using lung CT image data sets of real human body

Test protocol summary

Prepared five lung CT image data sets of real human body. Performed five pulmonary lobes segmentation and volume calculation manually using the validated segmentation tools in order to obtain the reference volumes of five pulmonary lobes for each test data set. Then performed air supply region approximation of each lung lobe by specifying the root of each bronchus and compared the measured results with the reference volumes.

Acceptance criteria

Pass if the measured values are within ±10% of reference values.

Test Results: The planned test cases have passed. It has been confirmed that the values obtained in the lung volume analysis have expected accuracy and can be used clinically.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act. Our device has similar indications for use, technology, labeling and testing as the predicate device. Therefore, we conclude that our device is as safe and effective as the predicate device.

Mr. Jyh-Shyan Lin
Senior Manager, Regulatory, Quality and Clinical Affairs
FUJIFILM Medical Systems, U.S.A., Inc.
419 West Avenue
STAMFORD CT 06902

JUN 1 4 2012

Re: K120648
    Trade/Device Name: Synapse 3D Lung and Abdomen Analysis
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: II
    Product Code: LLZ
    Dated: April 26, 2012
    Received: April 27, 2012

Dear Mr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
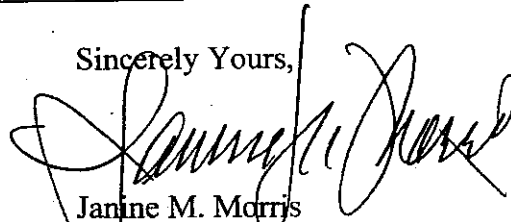
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
 Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Synapse 3D Lung and Abdomen Analysis

Indications for Use:

Synapse 3D Lung and Abdomen Analysis is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Lung and Abdomen Analysis accepts DICOM compliant medical images acquired from CT.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to Synapse 3D Base Tools, Synapse 3D Lung and Abdomen Analysis is intended to;

> use non-contrast and contrast enhanced computed tomographic images of the lung, provide custom workflows and UI, and reporting functions for lung analysis including boundary detection and volume calculation for pulmonary nodules in the lung based on the location specified by the user, segmentation of bronchial tubes in the lung, approximation of air supply region by the user specified bronchial tube, identifying, displaying and processing low absorption regions in the lung.

> use non-contrasted CT images and calculate subcutaneous fat and visceral fat areas in 2D and both volumes in 3D.

Prescription Use ___X___   AND/OR   Over-The-Counter Use

(Part 21 CFR 801 Subpart D)   (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K120648

Page 1 of 1